

REMARKS

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, 28, 29, 31, 34, 36, 39-41, 46, 49, 51, 64, 66, 67, 69-77, 79, and 80 are now in the application. By this Amendment, claims 29 and 36 have been amended. Support for the amendment to claim 29 is found at least at original claim 61 and at page 22, lines 12-27, of the specification. Claim 36 has been amended to correct a clerical error. Claim 80 has been added. Support for claim 80 is found at least at lines 1-4 of claim 29. Claim 61 has been canceled without prejudice or disclaimer. Claims 29, 31, 34, 36, 39-41, 46, 49, 51, 64, 66, 67, 69-77, 79, and 80 are directed to the elected invention. Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, and 28 are directed to non-elected invention and may be canceled by the examiner upon the allowance of the claims directed to the elected invention. No new matter has been added.

Prior to addressing the rejections in the Office Action, and in support of the patentability of the pending claims, Applicants provide the following arguments in reply to the “Response to Applicant’s Arguments” at pages 8-10 of the Office Action.

At page 8, second paragraph, the Office Action states that the composition of claim 29 does not necessarily require a polyol.

In the composition according to claim 29, the total content of at least one member selected from the group consisting of a fat component, an oil component and a polyol is not lower than 50% by weight based on total weight of the composition minus a weight of coenzyme Q₁₀. Therefore, claim 29 reads on an embodiment containing no polyols in the composition, as long as the total content of the fat component and/or the oil component is not lower than 50% by weight.

The Office Action further states, at the above-indicated paragraph, that polyglycerol fatty acid ester is an optional component. However, claim 29 has been amended herewith to recite that a content of the polyglycerol fatty acid ester is not lower than 1% by weight. Thus, it is respectfully submitted that polyglycerol fatty acid ester is a mandatory component of the composition according to claim 29.

Moreover, the Office Action states that Tween and/or Span species are optional components.

It is respectfully submitted that it is preferable if the claimed composition does not contain Tween and/or Span species because Tween and/or Span species inhibit the reduced coenzyme Q₁₀-stabilizing effect attained by the fat component, the oil component and the polyol. However, it is acceptable if the composition contains an amount not higher than 30% by weight of Tween and/or Span species. See page 10, lines 17-28, of the specification.

In addition, the Office Action states that the claims do not require the limitations of degree of stability or absorbability of the reduced coenzyme Q₁₀. However, claim 29 has been amended herewith to recite the features of claim 61.

It is one benefit of the claimed subject matter that the absorbability of the reduced coenzyme Q₁₀ can be increased without inhibiting the reduced coenzyme Q₁₀-stabilizing effect against oxidation, which is attained by the fat component, the oil component and the polyol. By the above discussed amendments, the percentage of retention of red reduced coenzyme Q₁₀ is positively recited and the stabilizing effect against oxidation has been made clearer.

At page 9, first paragraph, the Office Action states that Motoyama suggests that drug formulations can be stabilized.

However, as previously noted, Motoyama merely suggests dispersion stability and bioavailability, but neither discloses nor suggests the reduced coenzyme Q₁₀-stabilizing effect against oxidation.

At page 9, second paragraph to page 10, first paragraph, the Office Action states that the scope of claims is not commensurate with the showing in the declaration filed in this application on October 29, 2009.

However, Examples 23-25 in the present specification show the results when 0% by weight of Tween and/or Span species were used. Moreover, the Examples in the specification

and experimental results in the Declaration fully demonstrate the excellent effects of the present invention. Therefore, it is respectfully submitted that the scope of claims is commensurate with the results shown in the Examples and the Declaration.

Claims 29, 31, 34, 36, 39-41, 46, 49, 51, 61, 64, 66, 67, 69-77 and 79 are rejected under 35 USC §103(a) as being unpatentable over WO 01/52822 to Chopra in view of US Patent No. 4,751,241 to Motoyama et al.

Claim 29 recites a reduced coenzyme Q₁₀-containing composition which comprises (a) reduced coenzyme Q₁₀, (b) at least one member selected from the group consisting of a fat component, an oil component and a polyol, and (c) a polyglycerol fatty acid ester; wherein a content of the component (b) is not lower than 50% by weight based on total weight of the composition minus a weight of coenzyme Q₁₀, and a content of the component (c) is not lower than 1% by weight and not higher than 40% by weight based on total weight of the composition minus a weight of coenzyme Q₁₀. At least this combination of features cannot reasonably be considered to be taught or to have been suggested by Chopra, Motoyama, or any permissible combination thereof.

It is respectfully submitted that by using the specific components and contents, the instantly claimed subject matter can obtain the reduced coenzyme Q₁₀-containing composition having improved absorbability without inhibiting the reduced coenzyme Q₁₀-stabilizing effect against oxidation.

As previously noted, Motoyama only describes improving dispersion stability and absorbability of a drug, which is very slightly soluble in water, by using the polyglycerol fatty acid ester. However, Motoyama neither discloses nor suggests that the polyglycerol fatty acid ester affects the reduced coenzyme Q₁₀-stabilizing effect against oxidation.

Therefore, it is unobvious to use the above specific components and contents of the present invention in order to obtain the excellent reduced coenzyme Q₁₀-stabilizing effect against oxidation and the excellent absorbability at the same time.

Claim 29 further recites that a percent retention of reduced coenzyme Q₁₀ after 3 days storage in the air at 40°C under a light-shielded condition is not lower than 70%, with the percent retention in the corresponding composition composed of reduced coenzyme Q₁₀, and at least one member selected from the group consisting of the fat component, the oil component and the polyol alone after storage under the same conditions being taken as 100%. These features of amended claim 29 can also not reasonably be considered to be suggested in Chopra and/or Motoyoma.

As appreciated by the Examiner, Chopra fails to explicitly suggest reduced coenzyme Q₁₀ in combination with a polyglycerol fatty acid ester. Nevertheless, the Office Action states that polyglycerol fatty acid esters are only optional components. However, as noted above, claim 29 has been amended herewith to recite that a content of the polyglycerol fatty acid ester is not lower than 1% by weight.

Motoyoma fails to explicitly suggest a composition comprising reduced coenzyme Q₁₀. Nonetheless, the Office Action relies on col. 2, line 56, of Motoyoma for suggesting ubiquinone, as the oxidized form of coenzyme Q₁₀. Further, the Office Action contends that the compositions may contain reducing agents, the presence of which would result in the formation of reduced coenzyme Q₁₀. However, it is respectfully submitted that Motoyoma fails to suggest features that can reasonably be considered to correspond to the above-quoted percent retention of reduced coenzyme Q₁₀ of amended claim 29.

Claims 29, 31, 34, 36, 39-41, 46, 49, 51, 61, 64, 66, 67, 69-77 and 79 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 16-19 of co-pending US Patent Application No. 11/586,511.

Claims 16-19 have been canceled with the response filed in co-pending US Patent Application No. 11/586,511 on October 28, 2011. Accordingly, this rejection is moot.

Claims 31, 34, 36, 39-41, 46, 49, 51, 64, 66, 67, 69-77, 79, and 80 are in condition for allowance for at least their respective dependence on an allowable claim 29, as well as for the separately patentable subject matter that each of these claims recites.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicants concurrently herewith submit the requisite fee for a Petition for a one-month Extension of Time. Applicants believe no additional fee is due with this response. However, if any such additional fee is due, please charge our Deposit Account No. 22-0185, under Order No. 21581-00490-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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